641—4.7(136A) Iowa registry for congenital and inherited disorders. The central registry provides active statewide surveillance for selected congenital and inherited disorders. Selected congenital and inherited disorders include birth defects and neuromuscular disorders.

4.7(1) *Definitions.*

a. Birth defects shall be defined as any structural or genetic abnormality that may adversely affect a child's health and development. The abnormality must be diagnosed or its signs and symptoms must be recognized within the first year of life.

b. Neuromuscular disorders include diagnoses involving the muscle, nerve, or neuromuscular junction.

4.7(2) *Surveillance policy for birth defects and neuromuscular disorders.*

a. Birth defects occurring in Iowa are reportable conditions, and records of these birth defects shall be abstracted pursuant to 641—1.3(139A) and maintained in a central registry.

b. Birth defects surveillance shall be performed in order to determine the occurrence and trends of birth defects, to conduct thorough and complete epidemiological surveys, to assist in the planning for and provision of services to children with birth defects and their families, and to identify environmental and genetic risk factors for birth defects.

c. Records for selected neuromuscular disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in a central registry. Selected neuromuscular disorders include Duchenne and Becker muscular dystrophies. Selected neuromuscular disorders surveillance shall be performed in order to determine the occurrence and trends of the selected neuromuscular disorders, to conduct thorough and complete epidemiological surveys through annual long-term follow-up, and to assist in the planning for and provision of services to children with selected neuromuscular disorders and their families for the period of time that adequate financial support is available for this project.

4.7(3) *Central registry activities.*

a. The center shall establish an agreement with the University of Iowa to implement the activities of the central registry.

b. The central registry shall use the birth defects and neuromuscular coding schemes defined by the Centers for Disease Control and Prevention (CDC).

c. The central registry staff shall review hospital records, clinical charts, physician's records, vital records and prenatal records pursuant to 641—1.3(139A) and any other information that the central registry deems necessary and appropriate for birth defects surveillance.

d. A reportable birth defect or neuromuscular disorder occurring in a fetal death or pregnancy termination may be included in the central registry.

4.7(4) *Department responsibility.*

a. When a live infant's medical records are ascertained by the central registry, the department or its designee shall inform the parent or legal guardian by letter that this information has been collected and provide the parent or guardian with information about services for which the child and family may be eligible.

b. The center and the central registry shall annually release aggregate medical and epidemiological information to medical personnel and appropriate state and local agencies for the planning and monitoring of services for children with birth defects.

4.7(5) *Confidentiality and disclosure of information.* Reports, records, and other information collected by or provided to the central registry relating to a person known to have or suspected of having a birth defect or neuromuscular disorder are confidential records pursuant to Iowa Code section 22.7.

Personnel of the central registry and the department shall maintain the confidentiality of all information and records used in the review and analysis of birth defects or neuromuscular disorders, including information which is confidential under Iowa Code chapter 22 or any other provisions of state law.

Central registry personnel are authorized pursuant to 641—1.3(139A) to gather all information relevant to the review and analysis of birth defects or neuromuscular disorders. This information may include, but is not limited to, hospital records, physician's records, clinical charts, birth records, death

records, fetal death records, prenatal records, vital records, and other reports relevant and necessary for birth defects and neuromuscular disorders surveillance.

No individual or organization providing information to the central registry in accordance with this rule shall be deemed or held liable for divulging confidential information.

4.7(6) *Access to information in the central registry.* The central registry and the department shall not release confidential information except to the following, under the following conditions:

a. The parent or guardian of an infant or child for whom the report is made and who can demonstrate that the parent or guardian has received the notification letter.

b. An Early ACCESS service coordinator or an agency under contract with the department to administer the children with special health care needs program, upon receipt of written consent from the parent or guardian of the infant or child.

c. A local health care provider, upon receipt of written consent from the parent or guardian of the infant or child.

d. A representative of a federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The information provided shall not include the personal identifiers of an infant or child with a reportable birth defect or neuromuscular disorder.

e. Researchers, in accordance with the following:

(1) All proposals for research using the central registry data to be conducted by persons other than program staff shall first be submitted to and accepted by the researcher's institutional review board. Proposals shall then be reviewed and approved by the department and the central registry's internal advisory committee before research can commence.

(2) The central registry shall submit to the central registry's internal advisory committee for approval a protocol describing any research conducted by the central registry in which the central registry deems it necessary to contact case subjects and controls.

f. A representative of a state agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state agency will be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa.